



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/510,869	10/07/2004	Russell Heinrich	2799	6233

Covidien
60 Middletown Avenue
North Haven, CT 06473

7590

10/28/2009

EXAMINER

EREZO, DARWIN P

ART UNIT	PAPER NUMBER
----------	--------------

3773

MAIL DATE	DELIVERY MODE
-----------	---------------

10/28/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/510,869	Applicant(s) HEINRICH ET AL.	
	Examiner Darwin P. Erez	Art Unit 3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 July 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 and 12-44 is/are pending in the application.
- 4a) Of the above claim(s) 26-43 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10, 12-25 and 44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. In view of the Appeal Brief filed on 7/10/09, PROSECUTION IS HEREBY REOPENED. New grounds of rejection are set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) initiate a new appeal by filing a notice of appeal under 37 CFR 41.31 followed by an appeal brief under 37 CFR 41.37. The previously paid notice of appeal fee and appeal brief fee can be applied to the new appeal. If, however, the appeal fees set forth in 37 CFR 41.20 have been increased since they were previously paid, then appellant must pay the difference between the increased fees and the amount previously paid.

A Supervisory Patent Examiner (SPE) has approved of reopening prosecution by signing below:

/ (Jackie) Tan-Uyen T. Ho/

Supervisory Patent Examiner, Art Unit 3773.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 6-9, 12, 15 and 44 are rejected under 35 U.S.C. 102(b) as being anticipated by US 6,162,244 to Braun et al.

Independent Claim 1: Braun discloses a stent delivery device capable of joining a first body vessel to a second body vessel, the device comprising an inner member 11 having a distal end portion and defining a longitudinal axis; an outer member 15 defining a lumen dimensioned to receive the inner member therein (see Figs. 4a-4c); and a radially expandable anchor (stent) 1 disposed at the distal end of the inner member, the expandable anchor having an initial condition wherein the expandable anchor is disposed between the outer member and the inner member (Fig. 4c) and an expanded condition (Fig. 4a); and a sheath 2 disposed about the expandable anchor for defining the shape of the expandable anchor in the expanded condition such that a distal end of the expandable anchor is radially larger than a proximal end portion of the expandable anchor in the expanded condition (see portion 20 in Fig. 3d).

Claims 6-8: The inner member is an inner tubular sleeve defining a central lumen extending therethrough (see Figs. 4a-4c), which is fully capable of permitting liquid to pass therethrough and drain through the inner tubular sleeve, and wherein the

inner tubular sleeve has a porous end 12, which is fully capable of permitting the transmission of moisture.

Claim 9: The expandable anchor is a hollow tube stent that defines at least one longitudinally oriented passage extending completely therethrough when in the expanded condition.

Claim 12: See grasper 12.

Independent Claim 15: Braun discloses a device for joining a first body vessel to a second body vessel (anastomosis device), comprising: a pair of concentric tubular sleeves including an outer sleeve 15 and an inner sleeve 11, each of the pair of concentric tubular sleeves having a distal end portion and a proximal end portion; and a radially expandable anchor (stent) 1 operatively disposable between the distal end portions of the pair of concentric tubular sleeves, the radially expandable anchor including a proximal end portion and a distal end portion capable of providing a radially outward force when the anchor expands. The stent of Braun is an expandable stent that is fully capable of providing an outer force to any connected tubular members.

Claim 44: The radially expandable anchor is fully capable of providing a radially outward force along the length of the anchor when said anchor expands.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 2, 16-17, 20-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Braun et al., as applied to the rejections above, and in view of US 5,222,964 to Cooper.

Braun discloses all the limitations of the claims, as seen in the rejections above, except for the radially expandable anchor stent being made from at least one sponge-like and a foam-like material. However, forming stents from sponge like material is well known in the art. For example, Cooper discloses a stent made from soft sponge rubber (col. 2, ll. 19-21). Therefore, it would have been obvious to one of ordinary skill in the

art at the time the invention was made to modify the stent of Braun to be made from a sponge-like material since Cooper discloses that forming a stent from such a material is well known in the art and since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960).

8. Claims 3, 4 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Braun et al. and Cooper, as applied to the rejections above, and in view of US 5,617,878 to Taheri.

The modified device of Braun discloses all the limitations of the claims except for the stent having a frusto-conical shape in the expanded position. However, having stents with a frusto-conical shape is well known in the art, as disclosed by Taheri in col. 5, ll. 24-26 and Fig. 13. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Braun to have a frusto-conical shape since having a stent with a frusto-conical shape is well known in the art, as taught by Taheri, and since it has been held that changing the shape of a working part involves only routine skill in the art. *In re Dailey*; 357 F.2d 669, 149 USPQ 47 (CCPA 1966).

9. Claims 5 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Braun et al. and Cooper, as applied to the rejections above, and in view of US 6,699,274 to Stinson.

The modified device of Braun discloses all the limitations of the claims except for the stent expanding upon contact with moisture. However, having stents with a moisture-controlled expansion is well known in the art, as taught by Stinson in col. 2, ll. 35-37. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Braun to have a moisture-controlled expansion rather than an automatic self expansion since such an expansion is well known in the art, as disclosed by Stinson, and that the timing of the expansion would merely be dependent upon the intended use for the stent.

10. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Braun et al., as applied to the rejections above, and in view of US 5,702,419 to Berry et al.

Braun discloses all the limitations of the claims except for the device having control unit. However, the use of a control unit for delivering a stent remotely is well known in the art, as shown in Fig. 1 of Berry. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Braun to have a control unit as it would allow the surgeon to deploy the stent remotely.

11. Claims 13, 14 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Braun et al. and Cooper, as applied to the rejections above, and in view of US 5,059,211 to Stack et al.

12. The modified device of Braun discloses all the limitations of the claims except for the stent being bioabsorbable (dissolves after a predetermined period of time). However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Braun to be made of a bioabsorbable

Art Unit: 3773

material since forming a stent from bioabsorbable material is well known in the art, as taught by Stack, and since it would allow for the removal of the stent from the body without any additional surgery.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darwin P. Erezzo whose telephone number is (571)272-4695. The examiner can normally be reached on M-F (8:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Darwin P. Erezzo/
Primary Examiner, Art Unit 3773